

REMARKS

I. Status Summary

Claims 1-134 were filed with the application. Claims 1-134 have previously been cancelled and claims 135-157 added. Claims 140, 147, and 154 have previously been cancelled. Thus, claims 135-139, 142-146, 148-153, and 155-157 are pending and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 135-139, 142-146, 148-153, and 155-157 presently stand rejected.

Claims 135-139, 142-146, 148-153, and 155-157 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 135-139, 142-146, 148-153, and 155-157 have been rejected under 35 U.S.C. §112, second paragraph, upon the contention that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claims 135-139, 142-146, 148-153, and 155-157 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 2 and 6 of U.S. Patent No. 6,617,114 (hereinafter referred to as "the '114 Patent") to Fowlkes et al.

Claims 135 and 148 have been amended herein. Support for the amendments to claims 135 and 148 can be found throughout the specification as filed, including particularly at page 37, lines 14-22; page 43, lines 8-29; page 45, lines 28-35; and page 94, line 30. No new matter has been added.

Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Response to the 35 U.S.C. §112, First Paragraph, Rejection of Claims 135-139, 142-146, 148-153, and 155-157

Claims 135-139, 142-146, 148-153, and 155-157 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Particularly, the Patent Office asserts that the “optional” step (b) is not supported in the subject specification.

After careful consideration of the instant rejection and the Patent Office’s basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants note that there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). Thus, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Patent Office to rebut the presumption. See Manual of Patent Examining Procedure (hereinafter “MPEP”) § 2163.04. Further, as a matter of Patent Office practice, the burden rests upon the Patent Office to establish a *prima facie* case of a failure to comply with 35 U.S.C. §112, first paragraph, with respect to the subject matter described and claimed in applicants’ patent application. See Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement (hereinafter “The Guidelines”), 66 Fed. Reg. at 1105. This includes “the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims”. *Id.* The Patent Office must establish “by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined in the claims”. *Id.* at 1107, citing *Wertheim*, at page 263. The Patent Office, therefore, must have a reasonable basis to challenge the adequacy of

the written description, and, in rejecting a claim, the Patent Office must set forth express findings of fact which support the lack of written description rejection.

Applicants respectfully submit that the Patent Office has not met this burden. However, in an effort to expedite prosecution, independent claim 135 has been amended herein to recite method of predicting the receptor-modulating activity of a test compound when bound to a receptor comprising, *inter alia*, providing an unliganded estrogen receptor, and contacting the unliganded estrogen receptor with a plurality of reference compounds. Support for the amendment to independent claim 135 can be found throughout the specification as filed, including particularly at page 37, lines 14-22; page 43, lines 8-29; and page 45, lines 28-35. No new matter has been added. The Patent Office concedes at page 3 of the Official Action that an "unliganded" receptor is supported in the specification of the subject patent application.

Accordingly, the instant 35 U.S.C. §112, first paragraph, rejection of independent claim 135 as allegedly failing to comply with the written description requirement is believed to have been addressed.

Claims 136-139, 142-146, 148-153, and 155-157 depend directly or indirectly from independent claim 135. Accordingly, applicants respectfully submit that the instant 35 U.S.C. §112, first paragraph, rejection of claims 136-139, 142-146, 148-153, and 155-157 is also believed to have been addressed.

Thus, applicants respectfully request that the instant 35 U.S.C. §112, first paragraph, rejection of claims 135-139, 142-146, 148-153, and 155-157 be withdrawn at this time. A Notice of Allowance is also respectfully requested.

III. Response to the 35 U.S.C. §112, Second Paragraph, Rejection
of Claims 135-139, 142-146, 148-153, and 155-157

Claims 135-139, 142-146, 148-153, and 155-157 have been rejected under 35 U.S.C. §112, second paragraph, upon the contention that the claims are indefinite for

failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Particularly, the Patent Office asserts that claim 136 is unclear as to what constitutes a panel-based descriptor in the absence of positive definition or recitation in the specification. The Patent Office further asserts that there is no definition for Xaa in claim 148.

Initially, applicants respectfully submit that the Patent Office's burden under 35 U.S.C. §112, second paragraph, is to interpret the claims from the perspective of the skilled artisan in a manner consistent with the specification. See Phillips v. AWH Corp., 415 F.3d 1303 (Fed.Cir. 2005). Furthermore, only when a claim term is "insolubly ambiguous" (*i.e.*, completely incapable of understanding) should it be deemed indefinite. See Marley Mouldings, Ltd. v. Mikron Industries, 417 F.3d 1356, 1361 (Fed.Cir. 2005), which held that when a claim "is not insolubly ambiguous, it is not invalid for indefiniteness." See also Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed.Cir. 2004) ("We have held that a claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, *i.e.*, it is not insolubly ambiguous, it is not invalid for indefiniteness.").

Applicants respectfully submit that the reference to panel-based descriptors in claim 136 is not insolubly ambiguous when considered in view of the instant specification. However, without conceding to the assertions of the Patent Office, and in an effort to facilitate prosecution, claim 136 has been cancelled herein. Applicants reserve the right to file one or more continuing applications directed to the subject matter of cancelled claim 136. Accordingly, the 35 U.S.C. §112, second paragraph, rejection of claim 136 is believed to have been addressed.

The Patent Office also asserts that it is not clear whether the phrase "any amino acid" in claim 148 refers to any naturally-occurring or synthetic amino acid. In response, applicants assert that one of ordinary skill in the art after a review of the subject specification would be apprised of the intended definition of "any amino acid" as recited in claim 148. However, without conceding to the assertions of the Patent

Office and in an effort to facilitate prosecution, claim 148 has been amended to recite, *inter alia*, a method “wherein at least one panel member is a peptide comprising Leu-Xaa-Xaa-Leu-Leu wherein Xaa represents any naturally occurring amino acid.” Support for the amendment to claim 148 can be found throughout the specification as filed, including particularly at page 94, line 30. No new matter has been added. Accordingly, the 35 U.S.C. §112, second paragraph, rejection of claim 148 is believed to have been addressed.

Thus, applicants respectfully request that the instant 35 U.S.C. §112, second paragraph, rejection be withdrawn at this time. A Notice of Allowance is also respectfully requested.

IV. Response to the Obviousness-Type Double Patenting Rejection of Claims 135-139, 142-146, 148-153, and 155-157 in View of the ‘114 Patent

Claims 135-139, 142-146, 148-153, and 155-157 presently stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 6 of the ‘114 Patent.

Initially, it is noted that when an obviousness-type rejection is based on the claims of a cited patent or patent application in view of the teachings of other cited references, such a rejection can be properly addressed by arguments and/or amendments typically used to address the rejections based on a combination of references under 35 U.S.C. §103. See, generally, MPEP §804.

The rejection is respectfully traversed. Applicants respectfully submit that the specific recitation of the method of predicting the receptor-modulating activity of a test compound when bound to a receptor as recited in claims 135-139, 142-146, 148-153, and 155-157 of the subject application is not disclosed in claims 1, 2, and 6 of the ‘114 Patent. Rather, claims 1, 2, and 6 of the ‘114 Patent are directed to a method of identifying a ligand that can mediate the biological activity of a target protein.

To elaborate, applicants respectfully submit that claims 135-139, 142-146, 148-153, and 155-157 recite that the receptor-mediated activity of a test compound bound to a receptor can be predicted by using a panel to obtain a fingerprint corresponding to how the test compound interacts with the receptor in its various panel-modified conformations. The similarity of the fingerprint of the test compound to the fingerprint of a reference compound of known biological activity can then be calculated and used to predict the biological activity of the test compound. Further, applicants submit that the panel members act as probes to survey conformational changes in the receptor. This feature, namely, predicting the receptor-modulating activity of a test compound when bound to a receptor, is believed to patentably distinguish current claims 135-139, 142-146, 148-153, and 155-157.

Claims 1, 2, and 6 of the '114 Patent, on the other hand, appear to recite the use of competitive inhibition to identify ligands that inhibit the binding of a target protein to a bound partner ligand. Particularly, a first library comprising a plurality of ligands is screened to identify one or more ligands that bind a target protein, and a second library comprising a plurality of ligands is then screened for the ability to inhibit the binding of the first target-binding ligands. Thus, applicants submit that the claims of '114 Patent pertain to the identification of peptides that are competitive inhibitors with small molecule ligand inhibitors. Therefore, the '114 Patent is not believed to teach or suggest a method of predicting the receptor-modulating activity of a test compound when bound to a receptor.

Accordingly, applicants submit that the obviousness-type double patenting rejection of claims 135-139, 142-146, 148-153, and 155-157 over claims 1, 2, and 6 of the '114 Patent has been addressed. Thus, applicants respectfully request that the instant rejection be withdrawn at this time. A Notice of Allowance is also respectfully requested.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above amendments and remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

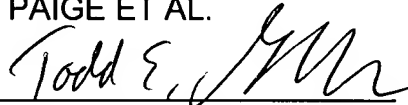
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any additional fees, or credit any overpayments associated with the filing of this correspondence to Deposit Account No. 23-1665, under Customer Number 27267.

Respectfully submitted,

LISA PAIGE ET AL.

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